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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,259	09/12/2001	Nestor Annibali	52071.00004	1187
7590 01/09/2006 Cameron Kerrigan SQUIRE, SANDERS & DEMPSEY L.L.P. One Maritime Plaza Suite 300 San Francisco, CA 94111-3492			EXAMINER JOIKE, MICHELE K	
			ART UNIT	PAPER NUMBER
			1636	
DATE MAILED: 01/09/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/955,259		ANNIBALI, NESTOR	
	<b>Examiner</b>		<b>Art Unit</b>	
	Michele K. Joike, Ph.D.		1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 October 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4 and 24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 is/are allowed.
- 6) ☒ Claim(s) 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7/29/05</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Receipt is acknowledged of a reply to the previous Office Action, filed October 21, 2005. Amendments were made to claims 4 and 24. Claims 1-3 and 5-23 have been canceled.

Claims 4 and 24 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed July 22, 2005, that is not addressed in this action has been withdrawn.

Applicant's arguments concerning the 35 U.S.C. 103(a) rejection of claim 24 have been considered. However, since that rejection has been withdrawn, the arguments are deemed moot.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

*Nature of the invention:* The nature of the invention is a method of obtaining the deposited yeast strain, ATCC PTA-2260, of claim 4. The method entails transforming any yeast cell with any vector comprising the specific elements listed, selecting Mut<sup>S</sup> yeast cells, isolating the strain of claim 4 and re-transforming it.

*Breadth of the claims:* The method of making the deposited strain of claim 4 is broad because any yeast cell can be used, and any vector, or DNA construction, can be used to make the strain, therefore a multitude of combinations exist.

*Guidance of the specification:* On pages 30-31 of the Specification, applicant states that any vector can be used. It could have a variety of selectable markers, and be linear or circular. Some of the working examples use specific vectors, but it varies from example to example, i.e. pPIC9 or pPICZ $\alpha$ A. Since the claim language itself is a "DNA construct", any vector could be used in this method.

Additionally, "a yeast cell" is transformed with the DNA construct. No specific yeast strain is mentioned in the claim. While the Specification states that *Pichia pastoris* GS115 (ATCC No. 20864) is the preferred strain to use, it also states that any methylotrophic yeast could be used, citing *Torulopsis*, *Hansenula* and *Candida*, as

Art Unit: 1636

examples. Also, GS115 is a strain that was obtained from Invitrogen. Because GS115 is obtained from Invitrogen, the strain may not be the exact same genotype as the strain deposited with ATCC.

*Predictability and state of the art:* Cloning with *Pichia pastoris* is well known in the art. However, since any vector and any yeast cell can be used, there are a vast number of vectors and strains available for use in this method. There are even several *Pichia* vectors that are available with the *AOX1* promoter (Invitrogen). pPIC9 and pPICZ $\alpha$ A are two of them. There are strains that are available for selecting expression vectors containing *HIS4* to generate the Mut<sup>S</sup> phenotype or for selecting zeocine resistant expression vectors with the Mut<sup>S</sup> phenotype (Invitrogen). Since any of these vectors or strains can be used, according to the Specification, it is highly unpredictable that the deposited strain ATCC PTA-2260 will be made.

In fact, with this method, applicant obtained clones that were *HIS*<sup>+</sup> and Mut<sup>S</sup>, which were not ATCC PTA-2260. ATCC PTA-2260 was just the “best yielding clone” (Applicant’s remarks 10/21/05). V8, 10.1 was a clone with the same phenotype of ATCC PTA-2260, with the difference being that it had 8 copies of the second DNA construct instead of 13 that ATCC PTA-2260 has. Therefore, any one of the clones that applicant made with this method could be produced when practicing this method, along with other clones not encountered by Applicant.

*Amount of experimentation necessary:* Since the steps listed in the method could produce a yeast strain that is not the exact same strain as deposited under accession number ATCC PTA-2260, undue experimentation would be required to

Art Unit: 1636

determine the genotype. Each clone would have to be sequenced to determine, for example, if it had one copy of the first vector, and 13 copies of the second vector. Indeed, applicants have not described the yeast strain deposited under ATCC PTA-2260 sufficiently so that the skilled artisan would be able to determine, without undue experimentation, whether any of the yeast strains made by the claimed method is exactly the same yeast (identical in all biochemical and physiological parameters) cell as the cells deposited at the ATCC under PTA-2260.

In view of the breadth of the claims and the lack of guidance provided by the specification as well as the unpredictability of the art, the skilled artisan would have required an undue amount of experimentation to make *Pichia pastoris* strain deposited under ATCC PTA-2260. Therefore, claim 24 is not enabled.

***Allowable Subject Matter***

Claim 4 is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

Art Unit: 1636

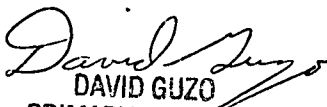
mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike, Ph.D. whose telephone number is 571-272-5915. The examiner can normally be reached on M-F, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele K Joike, Ph.D.  
Examiner  
Art Unit 1636

  
DAVID GUZO  
PRIMARY EXAMINER  
\* 2/21/10